DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Kaletra
Docket No. 01E-0089

The Honorable James. E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

MAR 10 2003

Dear Director Rogan:

This is in regard to the patent term extension application for U.S. Patent No. 5,886,036 filed by Abbott Laboratories, Inc. under 35 U.S.C. § 156. The patent claims the human drug product Kaletra (lopinavir), NDA 21-226.

In the September 21, 2001, issue of the Federal Register (66 Fed. Reg. 48687), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before March 20, 2002, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Steven F. Weinstock
Abbott Laboratories, Inc.
D377/AP6D-2
100 Abbott Park Road
Abbott Park, IL 60024-6050